Please add new Claim 36 as follows:

36. (new) A kit for use in detecting or diagnosing *P. aeruginosa*, wherein said kit comprises the composition of claim 9.

REMARKS

Claims 1-35 were pending. The Examiner has withdrawn Claims 10-17 from consideration as being directed to a non-elected invention (Office Action at § 3). The specification has been amended to insert a title, and section headings, and to correct typographical errors, in accordance with the Examiner's suggestions (Office Action at § 8). A marked-up version of the amended specification, in which deleted text is indicated by square brackets and added text is indicated by underlining, is attached hereto as Exhibit A.

Applicants have canceled Claims 2, 3, 5, 6, 10-17, 23, and 28-35, and amended Claims 1, 4, 7, 8, 9, 18-22, and 24-27 without prejudice to Applicants' right to pursue any canceled subject matter in other applications. Additionally, new Claim 36 has been added. These amendments are fully supported by the specification and claims as originally filed, and thus do not constitute new matter. In particular, the peptide fragments of SEQ ID NOS:1-2 (*i.e.*, SEQ ID NOS:3-5) are supported by, for example, the specification at page 2, lines 11-16, which provides for fragments of the proteins of the invention.

As such, claims 1, 4, 7, 8, 9, 18-22, 24-27, and 36 are pending. A marked-up version of the amended claims, in which deleted text is indicated by square brackets and added text is indicated by underlining, is attached hereto as Exhibit B. Further, a copy of the pending claims is attached hereto as Exhibit C.

Rejections Under 35 U.S.C. § 101

Claims 1-9 are rejected under 35 U.S.C. §101, as being directed to non-statutory subject matter (Office Action at § 9). Claims 2, 3, 5, and 6 have been canceled without prejudice. Independent Claim 1 has been amended to recite an isolated protein, as kindly suggested by the Examiner. Thus, Applicants respectfully assert that the rejections have been obviated, and request withdrawal of the rejections of Claim 1, 4, and 7-9 under 35 U.S.C. §101.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 2, 3, 5, 6, 8, 18, 22, 23, 25, and 26 have been rejected, under the first paragraph of 35 U.S.C. § 112, for allegedly lacking "sufficient and/or clear" written description (Office Action at § 10) and for lacking enablement (Office Action at § 11).

Applicants respectfully assert that the claimed subject matter is fully supported by an adequate written description as required by 35 U.S.C. §112, first paragraph. "The written description requirement, a question of fact, ensures that the inventor conveys to others that he or she had possession of the claimed invention; whereas the enablement requirement, a question of

law, ensures that the inventor conveys to others how to make and use the claimed invention." *Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶1, "Written Description" Requirement*, 66 Fed. Reg. 71427 (January 5, 2001). *See also Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 63 U.S.P.Q.2d 1609 (Fed. Cir. 2002). Further, there is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. *See, e.g., In re Wertheim*, 541 F.2d 257, 263, 191 U.S.P.Q. 90, 97 (C.C.P.A. 1976). Indeed, the invention need only be described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention. *See, e.g., Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560, 19 U.S.P.Q.2d 1111, 1114 (Fed. Cir. 1991). Thus, "[t]he fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed." *Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶1, "Written Description" Requirement*, 66 Fed. Reg. 71427 (January 5, 2001). *See also Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-4, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991).

Applicants note that independent Claim 1 recites an isolated *P. aeruginosa* protein of 60-65 kDa having an N-terminal sequence of specified amino acid sequences. In arguing that the written description requirement has not been met (*i.e.*, Applicants allegedly were not in possession of the invention), the Office Action maintains that "[t]he claimed product having the

recited N-terminal sequence and the function(s) is required." (Office Action at § 10). In response, Applicants submit that the specification and drawing clearly indicates that they were in possession of the invention at the time of filing. Moreover, there is no requirement that the complete sequence of the protein be described, or that the claims be limited only to disclosed sequences. *See, e.g., Union Oil Co. v. Atlantic Richfiled Co.*, 208 F.3d 989, 997, 54 U.S.P.Q.2d 1227, 1232 (Fed. Cir. 2000) ("The written description requirement does not require the applicant to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [the applicant] invented what is claimed.").

Possession may be shown in a variety of ways including description of an actual reduction to practice, such as by describing testing of the claimed invention. *Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶1, "Written Description" Requirement*, 66 Fed. Reg. 71427 (January 5, 2001). Indeed, the instant specification teaches isolation and characterization of Pa60 protein (*see, e.g.*, Example 1 of the instant specification). The purified Pa60 protein was then sequenced at its amino terminus (*see, e.g.*, Example 2 of the instant specification). Preparations of purified Pa60 protein were administered into animals to elicit an immune response, and enhance the clearance of infectious bacteria (*see, e.g.*, Examples 3 and 5 of the instant specification). Furthermore, Applicants used purified Pa60 protein in a clinical study to measure antibody titers to the protein in human subjects. Therefore, by particularly describing the isolation and testing of the claimed invention, the instant specification

clearly establishes possession of the claimed invention. As such, Applicants submit that the instant specification adequately describes the claimed invention as required by 35 U.S.C. §112, first paragraph, and respectfully request withdrawal of the claim rejections based on lack of written description.

Claims 2, 3, 5, 6, 8, 18, 22, 23, 25, and 26 have been rejected, under the first paragraph of 35 U.S.C. § 112, for allegedly lacking enablement (Office Action at § 11). Specifically, the Office Action appears to rely on the basis of lack of written description for maintaining an assertion that the invention is not enabled.

In particular, with respect to SEQ ID NOS:1-2 at page 2 of the instant specification, the Office Action alleges that "[t]here is no written description as to what amino acid residue each '?' stands for." Office Action at § 11. Applicants respectfully disagree. It is implicit from the disclosure that the question mark symbol indicates that any amino residue may occur at that position in the polypeptide. (The amendments to the specification made herein have amended SEQ ID NO:1 and SEQ ID NO:2 to be consistent with the claims). Even so, the Office Action asserts that "[e]ven after guessing the probable amino acids residues . . . [i]n the absence of the precise structural composition of the amino acid sequence of SEQ ID NO:1 and SEQ ID NO:2, one cannot make and use the claimed protein antigen or an antigenic fragment thereof." Office Action at § 11. Sequence motifs have long been considered patentable, however. Nevertheless, the claims have been amended in a manner that reduces the number of wildcard

positions to one or two. Coupled with the fact that the instant specification (*e.g.*, at page 2, lines 1-16) defines the claimed polypeptides as only those polypeptides that have a molecular weight of about 60-65 kDa, and that have an N-terminal sequence corresponding to the recited sequences, or parts thereof, Applicants submit that the claimed invention is sufficiently described and enabled.

Citing the teachings of Burgess *et al.* and Lazar *et al.* for support, the Office Action also asserts that:

> "[t]here is no guarantee that [variants of]an amino acid sequence or a fragment thereof would retain the desired antigenic properties and serve to be a diagnostic or a [*sic*] immunogenic vaccine composition. The art reflects functional unpredictability with regard to this. It is well known in the absence or deletion of, or the substitution of a single amino acid residue in a protein or a polypeptide can dramatically change or eliminate the function(s) of that protein or polypeptide and render it non-antigenic or antigenically non-specific." Office Action at § 11.

First, enzymatic activity is not at issue; therefore, reliance on Burgess *et al.* and Lazar *et al.* is inapposite. The claimed invention relates to a polypeptide composition that elicits an immune response. It is axiomatic that most amino acid substitutions do not significantly affect antigenicity.

Furthermore, that the claimed invention may encompass inoperative embodiments does not render the claims unenabled. Indeed, enablement is not precluded even if some experimentation is necessary. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947. This is so even if the amount of experimentation required is considerable and laborious. *In re Wands*, 858 F.2d at 731. In *Hybritech*, screening of hundreds of cells to find a single cell having the desired biological activity was deemed to be an acceptable amount of experimentation. Following the instant specification's teachings, the routine nature and amount of experimentation necessary to assess the antigenicity of polypeptide variants, in accordance with the invention, undercuts concerns of undue experimentation, and clearly would be deemed acceptable under *Hybritech*.

Finally, with respect to the enablement requirement and claim scope, it is well settled that the inclusion of undisclosed species within a claimed genus does not necessarily render a claim unduly broad. *Horton v. Stevens*, 7 U.S.P.Q.2d 1245, 1247 (Bd. Pat. App. & Int'f. 1988) ("The mere fact that a claim embraces undisclosed or inoperative species or embodiments does not necessarily render it unduly broad."). *Precision Metal Fabricators Inc. v. Jetstream Systems Co.*, 6 U.S.P.Q.2d 1704, 1709 (N.D. Cal. 1988) ("The enablement requirement does not require that the patent disclose the specific embodiment of the claim; a broad claim can be enabled by the disclosure of a single embodiment."). Also, disclosure of every operable species in a genus is not required to claim the genus, even in unpredictable arts. *See* M.P.E.P. §2164.03.

Thus, based on the weight of all the evidence detailed above, Applicants respectfully submit that the specification fully enables, within the meaning of 35 U.S.C. §112, the claimed genus.

In view of the foregoing, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §112, first paragraph.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 2, 4-8, 18, 19 and 21-27 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regard as the invention (Office Action at §§ 12-13). In particular, the Office Action finds informalities in Claims 2, 4, 6, 7, 18 and 21 for lack of proper antecedent basis. Further, the corresponding dependent claims to Claims 2, 4, 6, 7, 18 and 21 are similarly found non-compliant as being dependent on a informal base claim. Applicants submit that the claims, as amended, recite proper antecedent basis. As such, Applicants assert that the rejections under 35 U.S.C. §112 have been obviated, and withdrawal of the rejections is respectfully requested.

Rejections Under 35 U.S.C. § 102(b)

Claims 1, 7, 21, and 24 have been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Yamáno *et al.* ("Yamano"), Yoshinori *et al.* ("Yoshinori"), Brown *et al.* ("Brown"), Yamaguchi *et al.* ("Yamaguchi"), Sompolinsky *et al.* ("Sompolinsky"), Barbhaiya *et*

al. ("Barbhaiya"), Meyer *et al.* ("Meyer"), or Fernandes *et al.*("Fernandes") (Office Action at §§ 14-15). Claims 1, 7, and 9 have been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Yamano, Yoshinori, Yamaguchi, Barbhaiya, or Meyer (Office Action at § 16). Claims 1 and 4 have been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Sipos *et al.* ("Sipos") (Office Action at § 17). Claims 1, 4, 21 and 24 have been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by International Publication No. WO 93/24636 to Hancock *et al.* ("Hancock") (Office Action at § 18).

Applicants respectfully assert that the cited references fail to teach each and every element of the amended claims, and thus cannot anticipate the claims, which now recite an amino terminus corresponding to one of SEQ ID NOS:1-5. *See, e.g., Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989) ("Every element of the claimed invention must be literally present, arranged as in the claim. The identical invention must be shown in as complete detail as is contained in the patent claim."). In order to completely respond to the cited art in the Office Action, Applicants distinguish each cited reference below.

Yamono teaches the isolation and characterization of Outer Membrane Protein C (also known as OprC; Genbank Accession No. NP_252479), which has an N-terminal amino acid sequence, MEKRMSTQQR AAGNACPTAA FSFDPARLAQ RRRWAGAFAA. Therefore, the protein taught by Yamono is clearly different from any of the instantly claimed compositions and cannot anticipate or make obvious the present invention.

Yoshinori, Barbhaiya, and Meyer each describe a study of bacterial proteins involved in the regulation of cellular iron. Accordingly, the 66-kDa outer membrane protein taught by Yoshinori was identified by its iron-related function. Proteins corresponding to the *Pseudomonas* genome that are known to be involved in iron acquisition or metabolism are as follows:

FeoB [P] COG0370 Fe2+ transport system
FeoA [P] COG1918 Fe2+ transport system
FecR [PT] COG3712 Fe2+-dicitrate sensor, membrane component
Fur [P] COG0735 Fe2+/Zn2+ uptake regulation proteins
HcaA1 [PR] COG2146 Ferredoxin subunits of nitrite reductase and ring-hydroxylating dioxygenases
Ftn [P] COG1528 Ferritin-like protein
MntH [P] COG1914 Mn2+ and Fe2+ transporters of the NRAMP family

Applicants submit that the amino acid sequences of the above-identified *Pseudomonas* proteins do not demonstrate significant homology to the instantly claimed compositions, and thus fail to anticipate or make obvious the present invention.

Brown teaches the identification, cloning and sequencing of katB, a catalase from *P. aeruginosa*. The amino acid sequence information provided in the reference demonstrates no significant homology to the instantly claimed compositions, and thus fails to anticipate or render obvious the present invention.

Yamaguchi teaches antibody binding to a 60 kDa protein that is found in several

bacterial species, but is not present in *Neiserria gonorrhoeae* or *Staphylococcus aureus*. The reference has no peptide sequence information, and thus cannot anticipate or make obvious the polypeptides defined by Claim 1, as amended.

Sompolinsky teaches sixty-four *P. aeruginosa* antigens in crude water-soluble extracts. The reference has no amino acid sequence information, and thus cannot anticipate or make obvious the presently claimed invention.

Fernandes teaches recognition of several *P. aeruginosa* proteins by systemic antibodies. Fernandes does not disclose any amino acid sequence information, however, and thus cannot anticipate or make obvious the claims, as amended. Notably, the reported 58.5 kDa protein was not protective of infection, which is contrary to the teachings of the instant specification.

Hancock teaches an outer membrane protein of *P. aeruginosa* having a molecular weight of about 65 kDa, and fragments thereof, which can be used for diagnostics or as a vaccine. The reference does not appear to teach the amino acid sequence of this 65 kDa protein, however, and thus Hancock cannot anticipate or make obvious the amended claims.

Sipos describes a study of heat shock proteins and particularly characterizes *P. aeruginosa* GroEL (Genbank Accession No. AAB34346), which has an N-terminal sequence, MAAKEVKFGD SARKKMLVGV NVLADAVKAT LGPKGRNVVL. This amino acid sequence is not encompassed by the present claims. Therefore, the protein taught by Sipos

cannot anticipate or make obvious the instantly claimed compositions.

Accordingly, Applicants assert that the rejections under 35 U.S.C. §102 have been overcome, and therefore withdrawal of the rejections based on anticipation is respectfully requested.

Rejections Under 35 U.S.C. § 103(a)

Claims 1, 7, 19-21, 24 and 27 have been rejected under 35 U.S.C. § 103(a) as allegedly obvious in view of Yamano, Yoshinori, Brown, Yamaguchi, Sompolinsky, Barbhaiya, Meyer, Fernandes, Hancock, Sipos (Office Action at §§ 19-20). The claims have been amended to specifically recite an amino acid sequence motif at the amino terminus of the claimed polypeptide, and thus are not anticipated by the cited references. Applicants have distinguished each of the cited references above. Thus, taken alone or together, there is now no showing of suggestion or motivation, either in the cited references or in the ordinary knowledge of those skilled in the art, to modify any of the cited references so as to arrive at the claimed compositions, which are derived from polypeptides having one of the recited SEQ ID NOS at the amino terminus.

Furthermore, an assertion that it would have been obvious to the skilled artisan to combine the prior art to meet the claimed invention requires an objective reason to make the combination. *See* M.P.E.P. § 2143.01. Without more, the level of skill in the art cannot be relied

upon to provide the otherwise lacking suggestion to combine teachings. *See Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 U.S.P.Q.2d 1161 (Fed. Cir. 1999); *see also* M.P.E.P. § 2143.01. Therefore, since the art has not been demonstrated to provide the necessary suggestion to arrive at the claimed invention, the amended claims cannot be obvious in view of the cited references, either taken alone or in combination. *See, e.g., In re Rouffet*, 149 F.3d 1350, 1355, 47 U.S.P.Q.2d 1453, 1456 (Fed. Cir. 1998). As such, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 103(a).

Claim Objections

Claims 1 and 3 are objected to for reciting "60kDa" and "65kDa" rather than "60 kDa" and "65 kDa," respectively (Office Action at § 21). Claim 3 has been canceled without prejudice. Claims 1 has been amended in accordance with the Examiner's suggestions.

Claims 18-19 are objected to for reciting "in the detecting" rather than "in detecting" (Office Action at § 21). Claims 18-19 have been amended in accordance with the Examiner's suggestions.

Applicants submit that these amendments have addressed the Examiner's concerns, and accordingly, Applicants respectfully request withdrawal of the claim objections.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request withdrawal of the outstanding rejections and objections, and allowance of the pending claims.

Applicants do not believe that any fee, other than an extension of time fee, is required in connection with this submission. However, should any other fee be required, the Commissioner is hereby authorized to charge any such fee to Deposit Account 02-4377. Any further extension of time that may be required is hereby requested. Duplicate copies of this sheet are enclosed.

Respectfully submitted,

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EXHIBIT A
Marked-up version of the amended specification

On page 1, line 1, insert the following paragraph:

[ANTIGEN] ANTIGENIC COMPOSITION OF A PSEUDOMONAS AERUGINOSA PROTEIN

On page 1, line 5, insert the following paragraph:

BACKGROUND OF THE INVENTION

On page 1, line 29, insert the following paragraphs:

BRIEF DESCRIPTION OF THE DRAWING

Figure 1 depicts the separation of a protein preparation from *P. aeruginosa* by SDS-PAGE, and the position of Pa60 as visualized by staining.

DETAILED DESCRIPTION OF THE INVENTION

On page 2, line 6, replace the paragraph beginning with "In a preferred embodiment" with the following paragraph:

In a preferred embodiment the protein has the following N-terminal sequence:

[?] Xaa-E-E-K-[?] Xaa-[?] Xaa-L-[?] Xaa-[?] Xaa-[?] Xaa-[?] Xaa-[?] Xaa-[?] Xaa-[?] Xaa-V-V-[?] Xaa-N-A; and preferably:

[?] Xaa-E-E-K-T-P-L-T-T-A-A-[?] Xaa-A-P-V-V-[?] Xaa-N-A

On page 5, line 1, replace the paragraph beginning with "*Pseudomonas aeruginosa* bacteria" with the following paragraph:

Pseudomonas aeruginosa bacteria, strain 385 (Pa385), were harvested from overnight culture of 100 agar plates by scraping the plates followed by washing twice by centrifugation at 10,000 x g for [10min] 10 minutes at 4°C. A crude outer membrane preparation was obtained by extraction of the outer membrane component with buffered [Zwittergent] ZWITTERGENT 3-14 detergent and ethanol precipitation.

On page 6, line 5, replace the paragraph beginning with "Pa60 was purified" with the following paragraph:

Pa60 was purified using preparative polyacrylamide electrophoresis (PAGE). Preparative SDS-PAGE was performed using the BioRad model 491 [Prep Cell] PREP CELL (a continuous

elution electrophoresis apparatus) using a 9% T-1.42% C acrylamide/BIS (N, N'-methylene-bisacrylamide) separating gel with a 10ml 4% T-0.36% C acrylamide/BIS stacking gel polymerised in a 28mm (internal diameter) column. Fractions eluted from the column were concentrated by lyophilisation and analysed for protein content by analytical SDS-PAGE. Pa60 isolated using these conditions contained SDS which was subsequently removed by potassium phosphate precipitation. [fractions] Fractions containing Pa60 were pooled and dialysed prior to determination of protein concentration.

On page 7, line 17, replace the paragraph beginning with "This sequence provides" with the following paragraph:

This provides a sequence with the following definite amino acids:

1-2-3-4-5-6-7-8-9-10-11-12-13-14-15-16-17-18-19

[?] Xaa-E-E-K-[?] Xaa-[?] Xaa-L-[?] Xaa-[?] Xaa-[?] Xaa-[?] Xaa-[?] Xaa-[?] Xaa-V-V-[?] Xaa-N-A

On page 7, line 22, replace the paragraph beginning with "If one includes" with the following paragraph:

If one includes probable amino acids the following sequence is obtained:

1-2-3-4-5-6-7-8-9-10-11-12-13-14-15-16-17-18-19

[?] Xaa-E-E-K-T-P-L-T-T-A-A-[?] Xaa-A-P-V-V-[?] Xaa-N-A

On page 10, line 6, replace the paragraph beginning with "An enzyme linked" with the following paragraph:

An enzyme linked immunosorbent assay (ELISA) was used to measure antibodies to Pa60 in BAL and serum samples. Polysorb microtitre wells were coated with purified Pa60 at a concentration of 1μg per ml (one microgram per milliliter). The plates were washed five times in [PBS] phosphate buffered saline (PBS) containing 0.05% [tween 20] TWEEN 20 (a surfactant and spreading agent that is also known generically as Polysorbate 20) between incubation steps. The wells were blocked with skim milk in PBS-0.05% [Tween] TWEEN 20 for 60 [min] minutes. Wells were incubated for 90 [min] minutes with serum or BAL samples that were diluted in blocking buffer for analysis. Conjugated immunoglobulins used were rabbit anti-human IgG, IgA and IgM and wells were incubated with conjugated immunoglobulins for 90 [min] minutes. The plates were then developed. Human IgG, IgA and IgM were used to quantitate the antibody.

On page 15, line 16, replace the paragraph beginning with "In yet another" with the following paragraph:

In yet another particular embodiment, this invention provides a method for diagnosing *P. aeruginosa* in a subject suffering from cystic fibrosis. This method comprises bringing into contact one of the proteins, antigenic fragments or antigen compositions disclosed in this

invention with a biological sample obtained from a subject with cystic fibrosis. The biological sample is preferably a sample of mucous, [e.g.] *e.g.*, saliva. This method further comprises detecting the presence of antibodies to [P. aeruginosa] *P. aeruginosa* in such a sample by, for example, detecting binding between the antigens or fragments and antibodies which specifically bind such antigens or fragments, using detection means which are of common knowledge to those of skill in the art.

EXHIBIT B
Marked-up version of the amended claims

1. (amended) An [outer membrane protein antigen from *P. aeruginosa* having] isolated *P. aeruginosa* protein, wherein said protein has a molecular weight [in the range] of about [60kDa] 60 kDa to about [65kDa] 65 kDa, [as determined by SDS-PAGE] and wherein the N-terminal sequence of said protein comprises an amino acid sequence selected from the group consisting of:

Xaa Glu Glu Lys Thr Pro Leu Thr Thr Ala Ala Xaa Ala Pro Val Val Xaa Asn Ala (SEQ ID NO:2);

Glu Glu Lys Xaa Xaa Leu (SEQ ID NO:3);

Xaa Glu Glu Lys Thr Pro Leu (SEQ ID NO:4); and

Val Val Xaa Asn Ala (SEQ ID NO:5).

4. (amended) [An antigenic] A fragment of the protein [defined in] of claim 1.

7. (amended) [An antigen] A composition comprising the protein [defined in] of claim 1.

8. (amended) [An antigen] A composition comprising the [antigenic] fragment [defined in] of claim [4] 6.

9. (amended) [The antigen] A composition of claim 7 [which further comprises one or more other P. aeruginosa antigens] or claim 8, further comprising another *P. aeruginosa* protein or protein fragment.

18. (amended) A kit for use in [the] detecting or diagnosing [of] *P. aeruginosa* [comprising] , wherein said kit comprises the protein [defined in] of claim [1] 2.

19. (amended) A kit for use in [the] detecting or diagnosing [of] *P. aeruginosa* [comprising] , wherein said kit comprises the [antigenic] fragment [defined in] of claim 4.

20. (amended) A kit for use in detecting or diagnosing [of] *P. aeruginosa* [comprising] , wherein said kit comprises the [antigen] composition [defined in] of claim 7 or claim 8.

21. (amended) [A composition capable of eliciting] The composition of claim 7 or claim 8, wherein said composition elicits an immune response in a subject [comprising the protein defined in claim 1] when administered to said subject.

22. (amended) [A composition capable of eliciting] The composition of claim 9, wherein said composition elicits an immune response in a subject [comprising the antigenic fragment defined in claim 5] when administered to said subject.

24. (amended) The composition of [claim 21 which is a vaccine composition] claim 7 or claim 8, wherein said composition further comprises a pharmaceutically acceptable carrier.

25. (amended) The composition of [claim 22 which is a vaccine composition] claim 9, wherein said composition further comprises a pharmaceutically acceptable carrier.

26. (amended) The composition of [claim 23 comprising one or more adjuvants] claim 7 or claim 8, wherein said composition further comprises an adjuvant.

27. (amended) The composition of [claim 24 comprising one or more adjuvants] claim 9, wherein said composition further comprises an adjuvant.